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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/957,045	10/24/1997	SUSAN MARY DALUGE	PB1517US3	9530

23347 7590 12/18/2002

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ART UNIT	PAPER NUMBER
1624	29

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Date mailed
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 29

Application Number: 08/957,045
Filing Date: October 24, 1997
Appellant(s): DALUGE ET AL.

Gerald M. Murphy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/27/01.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct. However, issues 4 and 5 of the 35 USC 112, paragraph 2 rejection are dropped and hence claims 19-20 are no longer rejected under 35 USC 112.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 9 and 18-22 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8). However, as issues 4 and 5 are now dropped what is denoted as Group II no longer exists.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct. The underscoring in Claim 19, choice d should be ignored. That choice has a minor typographical error (missing an oxygen atom) but is correct in the actual claim 19 of paper 8.

(9) Prior Art of Record

USP 5087697	Daluge	2-1992
USP 4916224	Vince	4-1990

US 5049671	Daluge	9-1991
US 4988703	Norbeck	1-1991
US 5763607	Vince	6-1998
US 4857531	Borthwick	8-1989
US 4728736	Shealy	3-1988
EP 413544	Harnden	1-1997

Grant and Hackh's Chemical Dictionary, 5th edition page 444 and 445

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection under 35 USC 112, paragraph 2

Claims 9, 18 and 22 are rejected under 35 USC 112, paragraph 2 as being indefinite. There are three reasons that these claims are indefinite. All three reasons apply to all of claims 9, 18 and 22.

A. The term "phosphonyl" is indefinite. It is unclear what its actual scope is. Exacerbating the matter is that Appellants have asserted a definition for phosphonyl which is contrary to the generally accepted meaning, and contrary to the dictionary definition. Both of these are grounds for indefiniteness.

The analysis begins with the IUPAC rules. IUPAC rules states, "phosphonic acids:* $HP(=O)(OH)_2$ (phosphonic acid) and its P-hydrocarbyl derivatives. NOC Rule D-5.51." Therefore, e.g. $PhP(=O)(OH)_2$ would be Phenylphosphonic acid (the hydrocarbon is phenyl). The Hackh's Dictionary reference is provided, page 444, which states specifically, as an example, that $PhP(=O)(OH)_2$ is Phenylphosphonic acid .

Appellants do not dispute this definition of phosphonic acids. It is beyond this point that there is a divergence of views.

An acyl radical of an acid is the radical formed by removal of the OH. It is named by removing the suffix "-ic" and replacing it with "-yl". For example:

Acetic acid [$CH_3C(O)OH$] becomes Acetyl [$CH_3C(O)$-],

Benzoic acid [PhC(O)OH] becomes Benzoyl [PhC(O)-]

Methanesulfonic acid [CH_3SO_2OH] becomes Methanesulfonyl [CH_3SO_2-].

In each case, the OH is removed from the acid to form the acyl, and the suffix -ic is replaced by -yl.

By the same pattern, a phosphonic acid becomes Phosphonyl. Hence, a phosphonyl is formed by removal of the OH from $RP(=O)(OH)_2$ to give RP(O)(OH)-. However, as stated in the Final Rejection, R is not defined. It could be just H, meaning only the parent acid acyl HP(=O)(OH)-, or it might include the P-hydrocarbyl derivatives as noted above to give (Hydrocarbon)P(=O)(OH)-, or R might be something broader.

Thus, phosphonyl is RP(O)(OH)-, and what R constitutes is unclear. The specification provides no guidance on this question, nor has any guidance been located in the prior art of record. Appellants provide no guidance in their remarks either, as they do not agree that this is the correct radical. Hence it is vague, and this is the first reason of two reasons that the term is rejected under 35 USC 112, paragraph 2.

The second has to do with what the overall structure of the radical is.

Appellants in paper 12 stated that phosphonyl was $-PO(OH)_2$. In Paper 23, Appellants presented on page 8 a full drawing with names to support their reasoning

that phosphonyl was $-PO(OH)_2$. The middle item, H_3PO_4 was called "Phosphonic acid"! That is simply wrong. H_3PO_4 is phosphoric acid, and is known only by that name. The Hackh's Dictionary reference is provided (page 445) to demonstrate that H_3PO_4 is phosphoric acid. This error then lead to the other two errors. The item to the left is the dihydrogen phosphato group which was misnamed the "phosphoryl group"; there is no basis for such a name. To the right is called the phosphonyl group but is in fact (as will be shown below)the phosphono or phospho group. All three are thus misnamed in the response.

It is Appellants' assertion in the Appeal Brief that phosphonyl is $-PO(OH)_2$. Appellants present no evidence that the word phosphonyl denotes the radical $-PO(OH)_2$. Indeed, the Hackh's Dictionary reference page 444 shows that exact $-PO(OH)_2$ group and calls it "phospho" (first definition in Column 2) or "phosphono" (6th from last definition in column 2). These "phospho" and "phosphono" are is indeed are the ordinary names for the radical $-PO(OH)_2$. The examiner has never seen the $-PO(OH)_2$ group used with anything but one of those two standard dictionary names. But the specification did not say "phosphono" or "phospho", and that is clear evidence that the specification did not intend the $-PO(OH)_2$ to be denoted. Whatever was intended by the specification with "phosphonyl", it was not $-PO(OH)_2$. But since Appellants state that they intend $-PO(OH)_2$, and the claim uses a word which does not mean $-PO(OH)_2$, then clearly the claim does not reflect Appellants' intention, and for this reason too the claim is properly rejected under 35 USC 112, paragraph 2. While Appellant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947); *Ex*

Parte Clifford, 63 USPQ 19). Terms may not be "used in ways that are contrary to the accepted meanings in the art" (MPEP 2173.01). That is exactly what has occurred here.

With regard to the examiner's analysis that the phosphonyl radical is RP(O)(OH)-, Appellants in the Appeal Brief state, for the first time, that this radical is "a phosphinic group." This makes no sense whatsoever. There is no such thing as "a phosphinic group" or indeed any "...ic group." The suffix -ic is used for the parent acid itself, e.g. acetic acid or phosphonic acid or phosphinic acid. Its not used for the name of a group (moiety). Groups end with terms like –yl (e.g. acetyl) or –ene (e.g. methylene) or –o (e.g. phosphono), etc. Appellants are simply confused.

B. The term "glycosidic bond" is indefinite. There is no clear guidance as to what the term means in the context of these claims.

The claim is drawn to a process of preparing a compound of Formula VIII, which has one variable, R3. R3 can be many things, including individual moieties such as OH, and groups which themselves can have substituents, such as a carbocyclic group which can have assorted substituents. However, at the end of the entire R3 definition, just before the recitation of the step itself, there is a proviso which limits the definition. Thus, in order to understand the scope of the claim, one must understand what has been removed from the broad genus. One seeking to practice the general process but avoid the scope of the claim needs to know what the boundaries of the proviso are.

The proviso reads, "provided that such groups are not attached by a glycosidic bond." But, in this context, what specifically is being excluded? There are a single, double, triple, dative, and normalized bonds, etc. But "glycosidic bond" is a specialized

term, and in the context of these claims, it is impossible to tell precisely what is excluded.

First, one turns to the specification, but this gives no explanation at all of what the term means. Further, the specification gives no explanation of why such compounds were excluded, so that one could not reason backwards from the explanation for clues to what it means. For example, while the bond goes from the N-9 of the purine, it is unclear whether the "glycosidic bond" goes to a N, O or C. Further, no reference of record defines or even uses the term.

Appellants themselves have had a very difficult time explaining what the term means. And Appellants have repeatedly presented, as examples of what the proviso excludes, compounds which were never in the genus in the first place!

In Paper 12, Appellants said, "The examiner correctly notes that hexose is not present. For example, amines such as 1-aminoribose are excluded." This is very confused. The examiner had never said anything about hexose. The comment about "1-aminoribose" makes no sense, because 1-aminoribose doesn't fall into formula VII in the first place. Formula VII is a chloropurine; 1-aminoribose is not a purine at all. In the paper of 3/17/2000 (Paper 15), page 4 , Appellants gave "an example of a Glycosidic bond". However, this explanation of what constitutes a "glycosidic bond" only makes matters worse. The arrow that Appellants have labeled as being to a "glycosidic bond" in fact points to an ordinary single bond. Moreover, its application to the current claims is quite unclear. The claims are drawn to preparation of purine derivatives, but again, there is no purine in this structure. Further, the bond depicted is <u>not</u> the bond which attaches the R^3 as appears to be required by the claim language, but rather appears to

be a bond internally present within the R^3 moiety. Moreover, the remarks do not appear to be aware of this, referring to R^3 choices which are bound by N, i.e. which are substituted amines (note first full sentence on page 5 of the remarks). But that is impossible. R^3 cannot be bound by a N, unless that N is part of a heterocyclic ring as set forth in the last R^3 choice.

Beyond that, a single example cannot define a term because we do not know the intended scope. Everything that is embraced by this "glycosidic bond" language is outside the claim, but what is it?

Appellants presented in paper 23 a brand new diagram on page 6 which at least depicts a purine, but the original questions remain unanswered, and the remarks made about this have in fact made matters worse. For the third time, Appellants presented as an example of what the proviso excludes, a compound which does not fall within Formula VII in the first place. Specifically, the heterocyclic ring at the lower right has a hydroxymethyl substituent at the right side of the tertrahydrofuran ring. The claim lists 7 categories of substituents permitted (See Appendix, page 28, 4th to 2nd from last lines. None of those items will embrace the hydroxymethyl. That is, this example of what is intended to be excluded is again something which was never included by the main formula. But the proviso is supposed to exclude what is present in the claim. Further, Appellants have also not stated whether this is exactly what a glycosidic bond comprises, or whether this is just an example. That is, is the excluded R^3 only the one with this specific choice --- the ribose ---, or is this merely one example of a compound with a glycosidic bond? In this regard it is very important to notice that the proviso is recited in claim 22, which doesn't permit R^3 to be cyclic in the first place. Thus,

apparently, Appellants intend the "glycosidic bond" to be able to go to non-rings, contrary to the impression one gets from the example proposed. That is, any notion that the glycosidic bond must be to a ring is inconsistent with claim 22, which contains the same exclusion, but does not permit rings. Yet the examples given have all mentioned rings!

In the Appeal Brief, page 5, Appellants cite *Envirco* for the notion that one "consults the specification, the prosecution history and where relevant ... extrinsic evidence." Agreed. However, the specification is completely silent, no extrinsic evidence (reference of record) has been presented which defines the term, and the prosecution history, as shown above, is entirely muddled. That is, the three examples presented (in papers 12, 15 and 23) all point to species which were never embraced in the first place. Further, single examples cannot provide guidance as to the full scope.

The Appeal Brief at page 6 refers to "meaning of terms given in technical dictionaries..." Appellants have cited no technical dictionary.

On page 7, Appellants repeat the same structure as was presented in paper 23, but this time call it "exemplary of an excluded R3 group." As noted above, this structure was never permitted in the first place. And giving an example does not tell us the scope of the excluded material.

In the sentence bridging pages 6-7 of the Appeal Brief, Appellants for the first time attempt to say exactly what they mean. This definition has no actual support, since it refers to a reference which is not of record. Further, it appears from the wording that Appellants are not actually employing any standard definition, but instead have modified some definition in a manner which is not clear. Appellants' wording is, "...

except the bond in the instant application is a special type of unstable "aminal linkage" in which the oxygen of the aminal is the ring oxygen of a pyranose or a furanose." Thus, it is still unclear. For example, unstable under what conditions? How would one of ordinary skill in the art have ever known that this modified definition is what was intended? Still, the sentence does say "ring oxygen of a pyranose or a furanose." But that contradicts claim 22. As noted above and was pointed out in paper 24, claim 22 has this proviso and yet R3 cannot be either a pyranose or a furanose because both of those are rings, and claim 22 has R3 as "an acyclic group." Thus, what does the proviso in claim 22 exclude --- it cannot be excluding rings because claim 22 doesn't permit rings in the first place. Further, the wording of the sentence bridging pages 6-7 of the Appeal Brief is not clear. Does the "except" (second from last line of page 6, first word) expand the definition of glycosidic bond to include the material after the word "except", or does it narrow the definition, requiring this additional feature to qualify as a "glycosidic bond". The way the sentence is structured, it could be read either way.

In summary, the claims are drawn to synthesis of compounds of Formula VII, excluding those with a "glycosidic bond". There is no clear notion of which compounds are excluded. Appellants have provided several examples, none of which fall into Formula VII in the first place. Moreover, the definition in the Appeal Brief pointing to "pyranose or a furanose" is flatly inconsistent with the use in claim 22, which doesn't permit either ring in the first place.

C. The phrase, "an acyclic group, where such acyclic groups may be optionally substituted with substituents selected from the group consisting of C_{1-4} alkyl, C_{1-4} alkoxy ... etc. " gives improper alternative language, and thus it is unclear what the intent is for

all the material in the substituents list. An acyclic group simply means that it has no cycles. Thus, by its very nature, it could already have these substituents. Acyclic only requires that there be no rings present; it is already an extremely broad term. Thus, it is impossible to tell what the purpose of the substituent list is. If one looks at just the material before "may be", one gets the impression that any substituent can be present, so long as there are no cycles. But if one looks at the material after the "may be" one gets the impression that other substituents are not present, for otherwise, why is there a list? Thus, it is unclear whether substituents not on that list are to be included. If a) they are included, then the substituent list makes no sense, since it has no function in defining the substituted matter, since "acyclic group" already embraces e.g. "acyclic group with an alkoxy substituent.". If b) they are not included, then the "acyclic group" claim language is not really correct, since not any acyclic groups is actually meant.

In paper 23, Appellants shortened the list of substituents on the acyclic group by removing some of them, "but assert that the claim has not been narrowed in any manner". This is true under a), but false under b). But how is it that shortening a list does not narrow the claim language?

The question of why this substituent list exists was addressed, for the first time, in the Appeal Brief. It states, "Appellants means for the optional list of substituents to guide a skilled artisan to the substitutions on the acyclic group." This is very puzzling. A claim is supposed to define the invention; the specification is what provides guidance. By why is any guidance needed? An acyclic group simply has no cycles, and any moiety present which has no cycle is already included. Thus, no guidance would be needed. Appellants comments about guidance seem to imply there that there is something less

than any acyclic group intended, and that one needs guidance to determine what moieties can be present in the acyclic group and which cannot. But that is not what the claim says. Guidance belongs in the specification, and is needed when there is question as to meaning of the main claim language; that is not the case here. Instead, the presence of this list makes it very unclear whether Appellants really intended any acyclic group, which is what is recited.

In summary, if the claim language really means any acyclic group, period, then no guidance is needed since one of ordinary skill in the art knows exactly what that means, and thus the substituent list has no legitimate role. If the claim language means less than that, then it is misdescriptive, since acyclic simply means having no cycles.

References which were attached to the Appeal Brief are not of record and are not considered.

Rejections under 35 USC 103

Claims 9, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daluge '697 in view of Vince '224 or Daluge '671, further in view of Norbeck, Vince '607, Bothwick or Shealy.

The primary reference Daluge '697 discloses a process extremely similar to Appellants process in Column 8, lines 18-37, conversion of V to II via VI. Note that Z can be Cl (Column 7 line 64) and is in fact the only named choice for Z. R^2 can be formyl (Column 7, line 29), one of only two named choices. It is essential to note that it is this process which the examiner relies on to demonstrate obviousness. There are other

processes present in the reference, but these do not render the claimed process obvious and the examiner does not rely on them.

There are two differences. The first is that while the prior art does the reaction with the non-reacting amine protected (with R^3), and then removes it, the claimed process is done with the non-reacting amine not protected. This variation --- of doing it without the protecting group --- is shown in the first set of secondary references, Vince '224 and Daluge '671. See Vince '224 example 22, which corresponds in the last step in scheme 1, use of 6b. In Daluge '671, See Example 4, where again the amine in the 2 position of the pyrimidine is unprotected. Thus, this is a known procedure. One would certainly be motivated to do a procedure which reduces the number of steps, since now one does not have to put on and then remove the protecting group.

The other difference is that the claims as presently amended now require the use of aqueous acid for the orthoformate condensation. The primary reference has just the generic "with an agent serving to effect formation of the imidazoles ring" (column 8, lines 32-33). The second set of secondary references, Norbeck, Vince '607, Bothwick and Shealy all show this orthoformate plus aqueous acid directly. In Norbeck, see Column 11, 13-14. This is exemplified at Column 19, step G, which uses aqueous Hydrochloric acid, just as Appellants do. In Vince see Figure 1, cyclization of 3a. Ex 11 uses the same procedure. In Bothwick, see paragraph bridging columns 17-18, using the same procedure. In Shealy, see Example 1, which uses the same acid. These references thus show that the use of aqueous acid is conventional for orthoformate cyclizations, so that is how the primary reference text "with an agent serving to effect formation of the

imidazoles ring" would be understood. Further, it is also what Example 27, first step, uses in this reference; see column 23, lines 11-12.

The traverse begins by saying that there are "two processes" in the primary reference, denoted on page 16 of the Appeal Brief as Route 1 and Route 2. The process of Route 2 (example 4) is miswritten. It should have the Cl, not the cyclopropyl amino at the top of the molecules. It is not relevant to this rejection because this process corresponds to R2 = H, and the examiner relies on the R^2 = formyl teaching of the reference. It does not fall within the Column 8, lines 18-37 disclosure that the examiner relies on. And most critically, it does not have the trialkylorthoformate reagent that the claim requires. Thus, the example 4 process does not render the claims obvious, the examiner does not rely on it, and all of its alleged failings are not relevant to the patentability of the claims.

The other is called Route 1. This is closer, but it is still a very different process. The Column 8, lines 18-37 process consists of two steps. First, there is the cyclization to form the imidazole ring. Then there is the removal of the R3 protecting group (see column 8, lines 35-36). The example 27 process is different. It does start with the first step. It begins with the correct starting material, in protected form, and then cyclizes with the trialkylorthoformate plus aqueous acid, to give the purine (first part of first step of Route 1). At this point, however, it then reacts with the cyclopropyl amine (second part of first step of Route 1, i.e. below the arrow). That is, it converts the Z=Cl group to the R= cyclopropylamino group. Then, in example 28, the protecting group is removed. Thus, it differs from the Column 8, lines 18-37 process which the examiner relies on in

that it inserts into the middle the process of converting Z to R. It therefore does not end up with the product specified in the rejected claims. In other words:

Column 8, lines 18-37 Process: V to VI to II (Correct final product with 6-Cl).

Route 2, Example 27-28 Process: V to VI to III to IV (Wrong final product with 6-cyclopropyl amino).

Therefore, it can be seen that these two processes begin with the same first step, but then they radically diverge.

Thus, when Appellants argue that neither Route 1 nor Route 2 renders obvious the claims, they are correct, but neither of these has been relied upon. The route that has been relied upon, that of Column 8, lines 18-37, has not been addressed.

The declaration cannot overcome these problems, and is unpersuasive for the following reasons:

A. It gives conclusions without the actual experiments to back them up. A declaration which presents conclusions without supporting facts, is entitled to little or no weight, cf. *In re Etter*, 225 USPQ 1, 6; *In re Grunwell*, 203 USPQ 1055, 1059; *In re Buchner*, USPQ2d 1331; *In re Chilowski*, 134 USPQ 515,521; *In re Brandstadter*, 179 USPQ 286, 293-294, *In re Thompson*, 192 USPQ 275; *Ex parte George* 21 USPQ2nd 1058, 1062. There are references to "low yields" and "difficult separation", "complex mixture" etc, but no actual data to support this is presented. Appellants argue difficulties in removing the protecting group, but again, no evidence of this is actually presented. The removal of the protecting group in example 28 of the reference appears to have gone without difficulty.

B. Some material is not very clear. For example, Appellants state that "Compounds of formula (III) are more reactive to amines; thus a shorter reaction time is needed." Shorter than what?

C. Much of the discussion appears to have nothing to do with the claims. For example, while the attachment shows "Present Inventive Process" as (III) reacting with amine to give VI, that step is not part of the claims. Arguments based on steps that are not recited cannot be persuasive. Similarly, difficulties in isolating the product of the second part of example 27, the conversion of 6-Cl to 6-cyclopropylamino are irrelevant. The examiner does not rely on that step (conversion of 6-Cl to 6-cyclopropylamino) because the claims do not have such a step either. Similarly, Appellants state, "chlorination ... without blocking the amino ... results in tars." Again, chlorination is simply not part of the claimed process at all --- this is a step much further back in the sequence.

A proper declaration would just show the reaction done twice for a side by side comparison. The first way would be the method done in the rejected claims. The second would be the same process but done with the amino group protected, along with the removal of the protecting group. The protecting group should be the one used in example 27, step 1. It would be put on as done in the reference (see. E.g. example 23) and taken off as done in the reference (see example 28).

The remainder of the discussion goes through the secondary references (except Daluge '671 which is not discussed) discussing alleged problems here and there. However, these references are not there to themselves render the process obvious. Moreover, their problems are no necessarily at all related to the issues at hand. For

example, details of reaction procedure, or the specific substituents used in the secondary references, could have caused differences.

In the sentence bridging pages 18-19, Appellants state that no reference has the three features of unprotected amino, formyl protected amino at 5-position, and 4-Cl. This is correct, but such a reference would be an anticipation. All of those features are taught, albeit not all in the same reference. That is, the formyl protected amino at 5-position, and 4-Cl, are in the primary reference, the unprotected amino is in Vince '224 and Daluge '671.

Claims 9, 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norbeck, Vince '607, Bothwick or Shealy, in view of EP 413,544 or Daluge '697.

The primary references Norbeck, Vince, Bothwick or Shealy are discussed above. These have the non-reacting amine not protected, and all show this orthoformate plus aqueous acid to do the cyclization. The sole difference is that they use in the 5-position the unsubstituted amino, whereas Appellants use the formyl amino. However, the secondary references teach that both are alternatively useable for this cyclization. Note that Q in EP 413,544 and NHR^2 in Daluge '697 are both defined as being either amino or formyl amino. Thus, the prior art explicitly recognizes that either the amino or the formyl amino can be used in the cyclization. That specific teaching of equivalence provides the motivation.

The Appeal Brief says, "These references basically use the same procedure as described in Example 4 of Daluge '697. First, this statement is irrelevant, because in this rejection, Daluge '697 is just a secondary reference. Second, it is demonstrably false. As

noted above, example 4 unlike the claims and the references cited, does not use the trialkylorthoformate reagent. Thus, the characterization of the primary references is not accurate.

Appellants next state that the primary references "fail to suggest ... the substitution pattern present..." This point is repeated in the second full paragraph on page 24. True, but that simply means that the references do not anticipate.

Next, Appellants argue (sentence bridging pages 23-24) that the secondary references do not teach this process. Agreed, but these are just secondary references. They are not there to themselves teach the exact process of the claims, but rather to show that in this cyclization phase, that the amino and formyl amino groups are alternatively useable.

Appellants argue (paragraph bridging pages 24-25) a lack of motivation. The motivation is as explained, the fact that the secondary references clearly teach that there are two ways of doing this, with the amino or with the amino having a formyl group attached. Thus, one would be motivated to do it either way.

Appellants next argue "unexpected results", citing the Daluge declaration. However: The declaration makes no mention at all of the primary references Norbeck, Vince, Bothwick and Shealy. It is concerned exclusively with one of the secondary references, Daluge '697. Therefore, it cannot present evidence of unexpected effects with regard to this rejection, since the primary references of this rejection are never mentioned. There is also the matter of issues A, B and C mentioned above, and relevant here as well.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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December 3, 2002

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